K071451

# 510(k) SUMMARY
ASCLEPION LASER TECHNOLOGIES GmbH
TattooStar Y

AUG - 1 2007

This 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH TattooStar Y is submitted in accordance with the requirements of 21 CFR 907.92 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

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|---|---|
| Applicant: | ASCLEPION LASER TECHNOLOGIES GmbH<br>Am Semmicht 1A<br>07751 Jena, Germany |
| Contact Person: | Mrs Antje Katzer<br>Product Management and<br>International Regulatory Affairs |
| Phone:<br>Fax:<br>e-mail: | +49 3641 77 00 309<br>+49 3641 77 00 302<br>antje.katzer@asclepion.com |
| Preparation Date: | May 21th, 2007 |
| Device Name: | TattooStar Y |
| Common Name: | TattooStar Y |
| Classification Name: | Instrument, surgical, powered, laser<br>79-GEX<br>21 CFR 878.481 |
| Equivalent Device: | Medlite C6 |
| Device Description: | The TattooStar Y is a q-switched solid state lasers emitting wavelengths of 1064, 532 and 585 nm. It consists of a laser enclosure and optic delivery system (articulated mirror arm). |
| Intended Use: | The TattooStar Y is indicated for incision, excision, ablation and vaporization of soft tissue in general dermatology and the removal of tattoos, pigmented lesions, vascular lesions and unwanted hair. |
| Comparison to: | The TattooStar Y is substantially equivalent to the Medlite C6, with the same principles of operation, and the same indication for use. |

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| Nonclinical Performance Data: | None |
| Clinical Performance Data: | None |
| Conclusion: | The TattooStar Y is another safe and effective device for incision, excision, ablation, vaporization of soft tissue for general dermatology and the removal of tattoos, pigmented lesions, vascular lesions and hair. |
| Additional Information : | None |

EXHIBIT F

INDICATION FOR USE STATEMENT

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Asclepion Laser Technologies
% Antje Katzer
1A; IM SEMMICHT
JENA, GERMANY 07751

AUG - 1 2007

Re: K071451
Trade/Device Name: TattooStar Y
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 29, 2007
Received: July 2, 2007

Dear Antje Katzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: TattooStar Y

Indications for Use:

The TattooStar Y is intended for use for incision, excision, ablation, vaporization of soft tissue for general dermatology and the removal of tattoos, the removal of benign pigmented lesion, the removal of vascular lesion and the removal of hair.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071451

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)